

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
20-641/SE5-007**

Correspondence

SCHERING CORPORATION NDA NO 20641 S-0

NDA SUPPLEMENT S-5
DUPLICATE

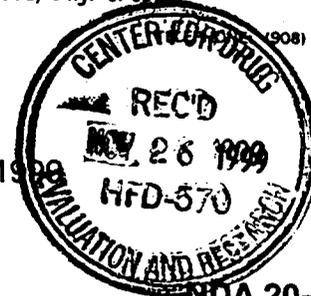
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KENILWORTH, N.J. 07033

(908) 298-4000

November 24, 1999



NDA 20-641

CLARITIN (loratadine) SYRUP

Robert Meyer, M.D., Director
Division of Pulmonary Drug Products
Center for Drug Evaluation and Research
HFD-570, Room 10B03
5600 Fishers Lane
Rockville, MD 20857

**SUBJECT: PEDIATRIC LABELING SUPPLEMENT
NON-FINAL SUBMISSION OF PEDIATRIC STUDY REPORTS**

Dear Dr. Meyer,

Enclosed is the first supplemental application to an approved NDA 20-641, CLARITIN (loratadine) SYRUP, in response to the Official Written Request for pediatric studies dated October 15, 1998 as amended November 17 and November 19, 1999 (attachment 1).

As part of this supplement, we are submitting the pharmacokinetic and safety studies required for pediatric subjects 2 to 5 years of age, which are identified as "Study 1" and "Study 2" in the official Written Request. Consistent with the Agency's guidance, since this is the first of multiple submissions in response to a Written Request, we are not requesting a pediatric exclusivity determination at this time. We intend to make additional submission(s) in response to the Written Request by June 30, 2000, and will mark the final submission consistent with the Agency's direction in the guidance, requesting a pediatric exclusivity determination.

This supplement includes a safety study (C98-566) in pediatric subjects 2 to 5 years of age with seasonal allergic rhinitis or chronic idiopathic urticaria. In addition, safety data from a pharmacokinetic study (C97-033) and pooled safety data from pediatric subjects 2 to 5 years of age from the original Claritin (loratadine) Syrup application (NDA 20-641) are discussed.

* Guidance for Industry, Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act, September 1999, Section VIII.

These studies demonstrated that a single 5 mg dose of loratadine syrup was safe and well tolerated in healthy pediatric subjects aged 2 to 5 years. No adverse events were reported during or following administration of loratadine. Evaluation of vital signs, electrocardiograms, and clinical laboratory tests did not reveal and clinically significant changes. In addition, daily 5 mg doses of loratadine syrup administered for 14 days to children with allergic rhinitis or chronic idiopathic urticaria were well tolerated, with a safety profile similar to that observed in older children.

The following sections of the labeling have been updated based on this supplement:

CLINICAL PHARMACOLOGY:

Pharmacokinetics:

Clinical Trials:

INDICATIONS AND USAGE:

PRECAUTIONS:

Pediatric Use:

ADVERSE REACTIONS:

DOSAGE AND ADMINISTRATION:

This supplement was prepared in accordance with 21 CFR 314.50, 314.70, and 201.57. The following guidances were also used in preparation of this supplement: The Content and Format for Pediatric Use Supplements and Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act.

Pursuant to 21 USC 379(h)(a)(1)(F) no fee is due upon submission of this supplement since it only proposes to include a new indication, to an approved product, for use in a pediatric population.

In accordance with 21 CFR 314.70 (a) Schering Corporation certifies that a copy of the technical section of this supplement is being sent to FDA's New Jersey District Office.

If you have any questions regarding this submission please contact Mary Jane Boyle at (908) 740-5693 or Daniel McHugh at (908) 740-6744.

Please be advised that the material and data contained in this submission are considered to be confidential. The legal protection of such confidential commercial material is claimed under the applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(j) as well as the FDA regulations.

Sincerely,



Joseph F. Lamendola, Ph.D.

Vice President

U.S. Regulatory Affairs

DM/sb



DEPARTMENT OF HEALTH & HUMAN SERVICES

Trout
Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-641/S-S-007

DEC - 9 1999

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Attention: Joseph F. Lamendola, Ph.D.
Vice President, U.S. Regulatory Affairs

Dear Dr. Lamendola:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Claritin (loratadine) Syrup 1mg/ml

NDA Number: 20-641

Supplement Number: S-007

Date of Supplement: November 24, 1999

Date of Receipt: November 26, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on January 25, 1999, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Pulmonary Drug Products, HFD-570
Office of Drug Evaluation II
Attention: Document Control Room 10B-03
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Sandra Barnes /S/
Sandra Barnes
Acting Chief, Project Management Staff
Division of Pulmonary and Allergy Drug Products,
HFD-570
Office of Drug Evaluation II
Center for Drug Evaluation and Research